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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,874	02/08/2001	Michael Wassenegger	MPG-1 DIV-1	6565
1473	7590	05/18/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			HELMER, GEORGIA L	
		ART UNIT		PAPER NUMBER
		1638		
DATE MAILED: 05/18/2004				

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/782,874	WASSENNEGGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-35, 37, 48, 64-70 and 72-74 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29-35, 37, 48, 64-70, and 72-74 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 20 May 2003, paper number 19, including the 1.132 Declaration of Michael Wassenegger.
2. Applicant has cancelled claims 40-41, 53-63, and 71, and amended claims 29-32, 35 and 37. New claims 72-74 have been added. Claims 29-35, 37, 48, 64-70 and 72-74 are pending, and are examined in the instant action. Applicant refers to adding claim 75, however no claim 75 is presented in the amendment.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Claim Rejections - 35 USC § 112 second.**

6. Claims 29-35, 37, 48, 64-70 and 73-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - Claim 29 (line 18) recites "transcription expression". What does this mean? How does it differ from "transcription"? All subsequent recitations of this language are also rejected.

***Claim Rejections - 35 USC § 112-1 - Written Description***

7. Claims 29-35, 37, 48, 64-70 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record

The claims are drawn to sequences that are at least 80% identical to SEQ ID NO: 1 that encodes a protein at least 80% identical to the coding sequence of SEQ ID NO: 2. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed enzyme activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

The claims are also a transgenic plant cell comprising a foreign nucleic acid stably integrated into the genome, wherein the nucleic acid molecule is a nucleic acid molecule coding an RNA molecule that is capable of serving as a template for RNA directed RNA synthesis, wherein the template nucleic acid is linked to appropriate regulatory elements. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed enzyme activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that

DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Applicant traverses saying primarily (Response, p. 9-12) that Example 5 and Figure 2 of the specification show possession of the claimed invention. Figure 2

Applicant's traversal is unpersuasive. Examiner disagrees. The given Southern blots merely show DNA hybridization, but do not show possession or provide written description of other RdRP sequences.

#### The Declaration of Michael Wassenegger

The Declaration of Michael Wassenegger has been thoroughly considered and is found not persuasive to overcome the rejection for lack of Written Description.

Applicant traverses saying that (¶ 6) the nucleic acid sequence of the RdRP of Nicotiana tabacum when compared to that of SEQ ID NO: 1, shows a 89.9% sequence identity, and that the amino acid sequence shows a 85.8% sequence identity.

Applicant's traversal is unpersuasive because for the specific example addressed (above) the 80% sequence identity holds true as a quality of the nucleic acids used. However, Applicant claims all nucleic acids having 80% identity, without reference to any specific structures. Sequences identified in the Wassenegger Declaration are not

set forth in the specification, as originally filed. Therefore, these sequences do not provide a Written Description.

Applicant traverses saying primarily that Examiner's reliance on Lilly is misplaced (Response. p.12), asserting that the claimed nucleic acids are structurally and functionally defined.

Applicant's traversal is unpersuasive. Applicants have not described the specific structural features that would confer RdRP activity.

***Claim Rejections - 35 USC § 112-Enablement***

8. Claims 29-35, 37, 48, 64-70 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, which has RdRP enzymatic activity, does not reasonably provide enablement for any sequences that are at least 80% identical to SEQ ID NO: 1 that encodes a protein at least 80% identical to SEQ ID NO: 2 . The specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, which has RdRP enzymatic activity, does not reasonably provide enablement for a SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, where that nucleic acid (transcription/expression) causes a reduction in synthesis of a RdRP. This rejection is maintained for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

The specification sets forth a gene represented as SEQ ID NO: 1. However, the specification does not indicate what structural or functional properties of SEQ ID NO: 1

would represent an identity gene other than that of SEQ ID NO: NO: 1 encoding SEQ ID NO: 2.

**The Declaration of Michael Wassenegger**

The Declaration of Michael Wassenegger has been thoroughly considered and is found not persuasive to overcome the rejection for lack of Enablement.

Applicant traverses, stating primarily (¶ 7 and 8) that the reference of Xie, (PNAS, 98, pages 6517-6519, 2001) teaches that the nucleic acid encoding tobacco RdRP possess RdRP activity, and that therefore the corresponding sequence of Nicotiana tabacum, which has a sequence identity of 80% or more to the SEQ ID NO: 1 encode polypeptide having RdRP activity. Applicant further asserts that the corresponding Arabidopsis thaliana sequence which has a sequence identity of 63.2% to SEQ ID NO: 1 encodes a polypeptide having RdRP activity.

Applicant's traversal is persuasive in part. It appears that the Xie reference supports enablement for at least 90% sequence identity of the DNA. Applicant shows that two specific nucleic acid sequences having approximately 80% sequence identity have RdRP activity. However, applicant claims all such sequences.

Applicant traverses saying primarily (¶ 10-12) that Xie discloses the suppression of inducible RdRP activity in transgenic tobacco into which an antisense of the homologous tobacco RdRP has been introduced. <sup>Applicant</sup> Affiant states that he made a transgenic tobacco plant comprising tomato RdRP and obtained similar results upon challenge of the plant. Applicant asserts that therefore, the specification enables production of a transgenic plant having RdRP activity.

Applicant's traversal is unpersuasive. It is not apparent that the method of Xie are identical to those of the instant case.

**Claim Rejections - 35 USC § 102**

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 72 is rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen, et. al., WO 90/12084, published 18 October 1990.

Jorgensen, et. al. teach a transgenic petunia plant comprising a CaMV driven chalcone synthase gene which is capable of serving as a template for RNA directed RNA synthesis (p. 35, line 28 to p. 37 line 34).

Accordingly, Jorgensen anticipates the claimed invention.

***Remarks***

11. No claim is allowed.
12. SEQ ID NO: 1 and 2 are free of the prior art of record.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638  
May 16, 2004



  
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